

NEW APPLICATION FOR AUTHORISATION / APPROVAL TO IMPORT RESTRICTED SUBSTANCES OR THERAPEUTIC PRODUCT CONTAINING RESTRICTED SUBSTANCE

Companies and its applicants must register with Client, Registration, and Identification Service (CRIS) with valid CRIS user rights in order to be able to submit applications on behalf of the company via apply@prism.

The applicant will also require a Corppass before he/she can login to PRISM to retrieve the application form. A person who drafts an application on behalf of his/her company and is not a Singaporean Citizen, Permanent Resident or Employment Pass holder can apply for a HSA PIN to login to PRISM. The Corppass or HSA PIN is necessary for authentication and authorization purposes.

Note: From 11 April 2021, the login process for Corppass has been changed to verify the user's identity via Singpass first before accessing and transacting with government digital services. While Singpass is used for logins, Corppass will continue to be the authorisation system for access to government digital services.

For more information on CRIS, please refer to

https://www.hsa.gov.sg/e-services/cris

For more information on Corppass, please refer to

http://www.corppass.gov.sg/

For more information on HSA PIN, please refer to

https://www.hsa.gov.sg/e-services/hsa-pin

1. The online form may take an average of 15 minutes to fill in.

The time taken varies depending on the number and sizes of the file attachments, configurations of your computer and network, internet performance, etc. Please note that the time stated above excludes time taken for preparatory work in relation to filling the online form (e.g. scanning documents for file attachments).

2. Mode of payment

Please note that there will be no refund of any payment made in relation to applications submitted through PRISM.

The modes of payment available are as follow:

- GIRO
- Non-GIRO: eNETS (Credit/Debit Card)

Payment by GIRO requires pre-registration. The <u>GIRO application form</u> is required to be submitted by post to the HSA Finance Department. The correspondence address can be found in the application form. The registration process will take around 3 to 4 weeks after the submission of the application form.



Application Form

Part 1. Company Particulars

This section requires the applicant to verify and fill in any other relevant information relating to the company.

(1) Company details such as **Name**, **Address**, **Telephone** and/or **Fax** will be pre-populated based on the registered CRIS records.

If you need to makes changes to this information, please submit the changes via the **"Amend Company Information**" module under the <u>amend@prism</u> on PRISM e-Service webpage.

- (2) Indicate if the Billing Address is the same as the Company Address.
- (3) If the Billing Address is not the same as **Company Address**, please fill in the **'Postal Code'** field and click the **'Retrieve Address'** button. The **Block/House No**, **Street Name** and **Building Name** will be populated.
- (4) Fill in the 'Level-Unit' field and any additional detail relating to the company in the 'Other Address Details' field. (*If applicable*)
- (5) Click 'Next' button to proceed to Part 2. Applicant Particulars section.

and a second			
1. Company Particulars			
1.1 Name : *	ABC Co Ltd.,!		
1.2 Location Code :	1		
1.3 Company Address			
1.3.1 Address Type : *	Local		
1.3.2 Postal Code : *	541111		
1.3.3 Block / House No :	111A	1.3.4 Level – Unit :	# -
1.3.5 Street Name :	RIVERVALE WALK		
1.3.6 Building Name :	MULTI STOREY CAR PARK		
1.3.7 Country :	SINGAPORE		
1.4 Tel : *	12345678	1.5 Fax : Your Fax No. is necessary for our future correspondence	
1.6 Is Billing Address the same	as the Company Address ? *	Yes	[◯] No
1.8 Unique Entity No.(UEN) :	PatchUEN1		
			Next Reset

Part 2. Applicant Particulars

This section requires the applicant to enter relevant information relating to the applicant particulars.

- (1) Applicant details such as name, NRIC / FIN, designation, Telephone/Fax/Handphone number and e-mail address.
- (2) Select the type of **Preferred Contact Mode**.

(Note: Please ensure that the relevant contact details above are entered for your preferred contact mode. Please note that the preferred contact mode is the mode which you will receive the final notification of this application.

During the course of this application, you will receive our Input Request (i.e. queries), if any, via email if you have indicated your email address above, regardless of your selected preferred contact mode.)

(3) Click 'Next' button to proceed to Part 3. Licence Information section.



Fields marked with an asterisk * are mandatory.

2. Applicant Particulars				
2.1 Name: *			(as in NRIC/FIN)	
2.2 NRIC/FIN: *		(Example: S12	34567A, F123456	7A)
2.3 Designation: *				
2.4 Contact Details				
2.4.1 Tel: *		2.4.2 Fax:		
2.4.3 Handphone:		2.4.4 Pager:		
2.4.5 Email:				
2.5 Preferences				
*	Email Fax SMS (Please ensure that the relevant contar this preferred contact mode is the mo course of this application, you will rec your email address above, regardless	de which you will eive our input rec	receive the final notifiquests (i.e. queries), if	ication of this application. During the any, via email if you have indicated
				Previous Next Reset

Part 3. Licence Information

This section requires the applicant to enter the following information as applicable:

- 3.1 Therapeutic Products Importer's Licence Number
- 3.2 Poisons Licence Number
- 3.3 Import of Clinical Research Material Notification Number
- 3.4 Product Registration Number
- 3.5 Consignment Approval for Registered Therapeutic Products
- 3.6 Other relevant approval numbers, as applicable

At least one of items 3.1, 3.2 or 3.3 should be entered.

Click 'Next' button to proceed to Part 4. Name of Person to Appear on Licence section.

Fields marked with an asterisk *	are mandatory.			
3. Licence Information				
3.1 Therapeutic Products Importer's Licence No : 3.2 Poisons Licence No :				
3.3 Import of Clinical Research Material Notification Number :				
3.4 Product Registration No :				
3.5 Consignment Approval for Registered Therapeutic Products :				
3.6 Other Relevant Approvals (Eg Medical Device Dealer's Licences, Special Access Routes) :				
		Previous	Next	Reset

Part 4. Name of Person to Appear on Licence

This section is optional. It is completed if the company wishes to have a person responsible for the import to be named in the authorisation / approval. The person indicated should be of sufficient authority to take responsibility for the import.

To proceed to the next section, Part 5. Exporter Particulars, click 'Next'.



4. Name Of Person To Appe	1 -	ith Sciences Authority
4.1 Name of person to appear on licence: (optional)		
	Previous Next F	Reset

Part 5. Exporter Particulars

This section requires the applicant to fill in the name and address of the exporter, mode of import (Air, Land or Sea) and proposed period of import.

Click 'Next' button to proceed to Part 6. Substances to be Imported section.

	· · · · · · · · · · · · · · · · · · ·
5. Exporter Particulars	
5.1 Name of Exporter :*	
5.2 Address of Exporter	
5.2.1 Address Type : *	Overseas
5.2.2 Address : *	
5.2.3 Province :	
5.2.4 State :	
5.2.5 City :	
5.2.6 Country :	Select Country
5.2.7 Postal Code :	
5.3 Telephone No :	
5.4 Fax No :	
5.5 Mode of Import :*	Select Mode 🗸
5.6 Proposed Period of Import :*	
	Previous Next Reset

Part 6. Substances to be Imported

- (1) In section 6(a), the applicant is required to fill in the following information:
 - 1) Brand/name of substance to be imported
 - 2) Total quantity of units to be imported
 - 3) Indicate "Yes" or "No" for diagnostic device or raw material
 - 4) Purpose of import. If "For other purpose" is selected, a text box will appear for the applicant to enter further details
 - 5) Present stock
 - 6) Country of re-export (if importing for re-export)
- (2) Click on the "Add Substance" button. The page will refresh showing the Substance Name in the "List of Substances Added". To remove any substance name that has been wrongly added to the "List of Substances Added", tick the box beside the Substance Name and click the "Remove Substance(s)" button.
- (3) Tick the box beside the substance name and click on the "Add/View/Update/Remove Ingredient(s)" button which will bring you to section 6(b) Ingredient Details.



б (a) Substances To Be Imp	orted
6.1 Brand/Name of Substance To Be Imported :	A
6.14 Total Quantity Of Units To Be Imported :*	1000.0
6.2 Diagnostic Device :*	Νο
(Please attach a list of	
diagnostic device/s)	
6.3 Purpose of Import :*	 For Local Consumption For Re-Export For Use as Clinical Research Material For other purpose (Eg Scientific Research / Animal Use / Destruction / Supply to ships and /or aircraft)
6.4 Raw Material :*	⊖Yes ●No
6.5 Present Stock :*	1
6.6 Dosage Form :	Select Dosage Form
6.7 Presentation :	Select Presentation 🗸
6.8 Pack Size and Quantity Of	
Packs :	
6.9 Country of re-export (if applicable) :	Select Country
Add New Substance	Update
List Of Substances Added	

List Of Substances Added					
Substance Name	Total Quantity Of Units To Be Imported		Raw Material	Purpose of Import	Total No Of Ingredients Added
	1000	No	No	For Local Consumption	No Ingredient Added
Remove Substa	nce(s)	Add/View/Update,	Remove Ingredie	nt(s)	

- (4) In section 6(b), the applicant is required to fill in the following information:
 - 1) Type the Active pharmaceutical ingredient name
 - 2) Quantity present in each unit
 - 3) Unit of measurement
- (5) Once all the information for the Ingredient Details has been entered, click on the "Add Ingredient" button. The page will refresh showing the Active Pharmaceutical Ingredient in the "List of Active Pharmaceutical Ingredient(s) Added". Check that the information on the list is correct. Click the "Back" button to return to section 6(a).

Previous Next Reset



Fields marked with an asterisk * a	are mandatory.		
6 (b) Ingredient Details			
6.9 Substance Name :	А		
6.10 Raw material :	No		
6.11 Active Pharmaceutical Ingredient(s) in INN Names :	ABC		
6.12 Quantity present in each unit :	1000		
6.13 Unit of measurement :	milligram(mg)	~	
6.14 Total quantity of units to be imported :	1000.0		
6.15 total quantity of substance to be imported :	100000.0		
Add New Ingredient	Update		
List of Active Pharmaceutical	Ingredient(s) Added		
Active Pharmaceutical Ingredient Name	Quantity present in each unit	Total Quantity of Substance To Be Imported	Unit of Measurement
ABC	1000	1000000	milligram(mg)
Remove			

Additional instructions:

- i. If the information displayed on the "List of Active Pharmaceutical Ingredient(s) Added" requires correction, click onto the name of the Active Pharmaceutical Ingredient on the list. The information on the Active Pharmaceutical Ingredient that has been selected will appear in section 6(b). Make the necessary correction and click the "Update" button when done. The updated information will now appear in the "List of Active Pharmaceutical Ingredient(s) Added".
- ii. To remove any Active Pharmaceutical Ingredient that has been wrongly added to the "List of Active Pharmaceutical Ingredient(s) Added", tick the box beside the Active Pharmaceutical Ingredient Name and click the "Remove Substance(s)" button.

Click 'Next' button to proceed to Part 7. Supporting Attachments section.

Part 7. Supporting Attachments

This section allows the attachment of any supporting documents for the application.

Add Supporting Attachments:

- (1) Click on the **Browse** button to select the required file for attachment.
- (2) Select the required file.
- (3) Click on the **Ok** button.
- (4) Click on the **Attach File** button for the file to be attached to this application.
- (5) Fill up remarks with regards to the attachment if required.
- (6) Click 'Next' button to proceed to Part 8. Confirmation and Declaration section.

Remove Supporting Attachments:

- (1) Click on the checkbox next to the attachment(s) from the **List of Attachments Table**.
- (2) To delete the attachment, click on the checkbox beside the attachment.
- (3) Click the '**Remove**' button.



Fields marked with an asterisk * are mandatory.

7. Supporting Documents		
To add an attachment, type in the to the list below.	path or hit the browse button. Then hit the Attach Files button to save	the attachment
Please click here for guideline on	document attachment.	
Documents		
7.1 List of diagnostic devices :		Browse
7.2 Other Supporting		Browse
Documents :		
Attach Files		
	Previous	Next Reset

The file extensions, which are acceptable and supported for attachments, are:

- tif (Black & White)
- pdf (Adobe Acrobat files)
- xls (Microsoft Excel files)
- avi (audio visual, if required)
- jpg (graphics files)
- doc (Microsoft Word files)
- ppt (Microsoft PowerPoint files)
- mpeg (audio visual, if required)

(Note: If the file size is too big (estimate about 2MB and above), the attachment time may take a longer time to upload.)

Part 8. Confirmation and Declaration

This section shows the information provided in all sections of the Application Form for Authorisation / Approval to Import Restricted Substances.

(1) The applicant is required to confirm that the information provided in all sections are correct and click the **'Validate'** button.

(Note: Applicant may click the '**Save**' button to save a copy of the draft application if he/she wishes to complete the application at a later time.)

- (2) Once validation is successful, the applicant is advised to read through the declaration carefully before accepting to undertake the conditions.
- (3) Click the 'Submit' button to submit the application.

All applicants under the Medicines Act (MA) / Health Products Act (HPA) must comply with the MA/HPA and their regulations. This is to ensure that all health products in Singapore meet the required standards of safety, quality and efficacy. Applicants must also comply with all other applicable laws and their regulations.

Declaration					
1. I, on behalf of my company, confirm that the information submitted in this application is true and accurate.					
Accept 🔿 Decline 🔿					
Payment Advice					
SnDescription		Amoun	t (SGD)GS	т	
1 Import Authorisation (Restricted Subs)			Y		
The total payment for your application is SGD					
The amount of SGD will be deducted from your Giro Account.					
	Previous	Validate	Submit	Reset	



Payment Advice

This section shows the application fee for the licence applied.

There are 2 modes of payment available:

- GIRO
- eNETS

Payment Advice		
Sn Description		Amount (SGD) GST
1 New App:		N
The total payment for your app	olication is	
The amount of	II be deducted from your Ciro Account.	
Payment Advice		
SnDescription		Amount (SGD)GST
and a subscription of the		and the second se
1 New App:		N
	lication is	
1 New App:	eNETS Credit Debit	N
1 New App: The total payment for your app	eNETS Credit Debit	N

For GIRO, the amount payable will be deducted from the relevant bank account. This mode of payment is a recurring deduction.

For eNETS, the payment choice is either Credit Card or Debit Card.

This is applicable for applicants with Non-GIRO Payment Method.

If the Credit option is selected, the page will be re-directed to the relevant screen for the applicant to input the credit card details.

e NETS			
eNETS	credit/debit ca. Pro are using a god-sp backs, passe dispersed, or your transaction request or 1. www.areds.ag	add the following list as your allowed spages from the banks may not be	Fast, Secure & Hassis-tree ansactions
Privacy Policy		MasterCard Vorified by	332
Security Guidelines	Merchant Name	Health Sciences Authority	
Customer Service	Merchant Reference Code NET's Reference Code Amount	ECT1700002K 20170109152942902 5GO 503.00	- 203
	important Notice: Please note down the t information in this section just in case yo raise any query on this transaction.	transaction ou need to	
	RECOLUCION CARD RECORDANCE		
	Name on Card Card Mumber	Contraction Contractica Contra	1.15
	Please note that the Criedt Card Number a Please input your card number althout spa CWV /	nound be 13 or 16 digits. ce or dash.	100
	CVC2	[What is CVVICVV2/CID]	
	Data Monte V	ig 2017)	
	 The return & refund p relevant products / se The collection, use, d information, which to and belief is true and reasonably required t 	d and accepted the following: olicy for the purchase of rivices. isclosure and sharing of this the best of my knowledge accurate and is for purposes o process my application IETS' Data Protection	
	And the second second second		

If the Debit option is selected, the page will be re-directed to the relevant screen for the applicant to select the bank first before being re-directed to input the debit card details. This mode of payment is a one-time deduction only.



e NETS		
Consumer ENETS Privacy Policy Security Guidelines Cuetomer Service	<section-header> Contraction of the second of the secon</section-header>	following list as your allowed sites, anks cannot be displayed, and your for pop-up blocker FAQ. account holders)
Please do not use your BACK or I CLOSE your browser while using	ELCAD/REFRESH proviser functions or Ins service	
© eNETS is a product of Netw	ork for Electronic Transfere (Singapore) Ple Ltd.	

Upon successful transaction, an eNETS official receipt and a HSA tax invoice will be generated.

	Official Receipt - H\$A000000000002 - Microsoft Internet Explorer	🛛
	🙄 lock - 🙄 - 🗷 😰 🏠 🔎 Search 👷 Favorites 🐠 Heda 🥹 😥 - چ 👼 - 🔜 🏂	a
TRANSACTION COMPLETE	Жны	~
Merchant Reference Code: ET161202113218180 NETS Reference Code: Date & Time: (TAX INVOICE / RECEIPT Receipt No HSA00000000002 Agency HSA-Heath Sciences Authority Application HSA-PAYMENT Paid via SP Ref No	
THANK YOU!	Sno Code/Description Unit Price(35) Qty	
TRRNSRCTION RHOLINT	1	
	Total (S\$):	
	This is a computer-generated receipt. No signature is required.	~

If the payment was made via eNETS and was not completed successfully, the system will prevent retrieval of the draft application and the applicant will need to contact <u>HSA HelpDesk</u> for assistance.





To submit the completed application, click the **'Submit'** button. Applicant will be prompt to confirm the submission. The application will then be submitted to HSA for the relevant personnel's processing.

<u>Acknowledgement</u>

This section acknowledges that the application has been submitted to HSA for processing. An application number will be generated for the successful application submitted.

Applicants may wish to print a copy of this acknowledgement page or take note of the <u>Application</u> <u>Number</u> for ease of reference. Applicants may provide the application number if they wish to communicate with HSA.

rour applic	ation have be	en successfully sub	omitted		
Please note	that your lice	ence applied is			
Please note	that your ap	plication numbers	1600375M		
Client Code					
Licensee	:				
Name					

Note: The show Printer Friendly version allows applicant to print or view the application.

Input Request

Input Requests arise when the reviewing HSA officer requires further clarification from the applicant regarding the application. This section illustrates how applicants can respond to the Input Request.

A notification will be sent to the applicant to inform the applicant to log in to <u>track@prism</u> to make the necessary changes.

Input requests can be classified as Primary or Secondary.

• <u>Primary Input Request</u> requires changes to be made directly on the application form.



• <u>Secondary Input Request</u> requires applicant's explanation to certain matters pertaining to the application form submitted.

Responding to Primary Input Request

(1) In <u>track@prism</u> enter the Application Number to retrieve the application that requires clarification.

PZ0951 TRACK@PRISM		
Important Notes: For HSA CRIS registered companies, user has to access the required eservices.	to be authorised with the appropriate access rights via CRIS management modul	e
General Search		
	ision No for fast and exact matched look-up	
Application/Submission Type *	New Application/Submission	
Licence/Permit/Certificate/Listing/Notificatio	n/Registration Restricted Substances - Import Authorisation	~
Enquiry Type *	Input Request	
Transaction No.		
Application/Submission No.	1600670D	
Licence/Permit/Certificate/Listing/Notificatio No.	n/Registration	
Product Name.		
Submission Date (dd/mm/yyyy)	То	
Last Update Date (dd/mm/yyyy)	То	
Search Reset		

(2) Click on the 'HSA Input Request' to view if any reply is required from the applicant. Click the 'Submit' button and an alert message will pop up to prompt you to make the necessary changes in the application form.

Transaction	Product	Application/Submission	Date	Last Updated	HSA Input
No	Name	Status	Required	Date	Request
Т1601220К	NA	Input Request	22/06/2016	14/06/2016	<u>Click here for</u> Primary IR (15/06/2016)
	No	No Name	No Name Status	No Name Status Required	No Name Status Required Date

Please do not access the record using the new window via right mouse click.

1 Matching Record(s)

Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

_ input i	Request List - Internet Explor	er	
🥘 https:	://www-uat. hsa.gov.sg /prism	n/common/InputReqActLi	(list.d Message from webpage
INPUTE	REQUEST LIST (PRIMA	RY)	
Applicati No	ion : 1600670D		Please click on the application number to make the necessary changes in the application form
Please al	eply with comments for ea lso update / amend the re ion no. on track@prism.		
Record			
Action Li SN	Action	Due Date	applicant's Response (if any)
Ι.	for manual	22/06/2016	
			Submit Cancel

(3) Click on the 'Application No.' to open the application.



S/No	Application No	Transaction No		Application/Submission Status		Last Updated Date	HSA Input Request
1	1600670D	T1601220K	NA	Input Request	22/06/2016	14/06/2016	<u>Click here for</u> <u>Primary IR</u> (15/06/2016)
Please do not access the record using the new window via right mouse click.							
Matchir	ng Record(s)					Page 1 Of 1 [First	st] [Previous] [Next] [La

- (4) The webpage will display the application form as per previously submitted.
- (5) Proceed to make the necessary changes for the section(s) that require clarification and submit the revised application form.

Responding to Secondary Input Request

(1) In <u>track@prism</u> enter the **Application Number** to retrieve the application that requires clarification.

PZ0951 TRACK@PRISM		
Important Notes: For HSA CRIS registered companies, user has to be to access the required eservices.	authorised with the appropriate access rights via CRIS management r	nodule
General Search		
Enter Transaction No or Application/Submission N	o for fast and exact matched look-up	
Application/Submission Type *	New Application/Submission	
Licence/Permit/Certificate/Listing/Notification/Regi Type ^y	stration Restricted Substances - Import Authorisation	~
Enquiry Type *	Input Request 🗸	
Transaction No.		
Application/Submission No.	1600670D	
Licence/Permit/Certificate/Listing/Notification/Regi No.	stration	
Product Name.		
Submission Date (dd/mm/yyyy)	то Т	
Last Update Date (dd/mm/yyyy)	то	
Search Reset	at	

(2) Click on the 'HSA Input Request' to view the comments left by the HSA officer and the necessary action to be taken with regards to the application.

/No	Application No		Licence/Registration No	Product Name	Application/Submission Status		Last Updated Date	HSA Input Request
1	1600783J	Т1601374К		NA	Input Request	11/07/2016	04/07/2016	Click here for Secondary IR (04/07/2016
	do not acces	s the record u	sin _. via	a right mo	ouse click.	Page 1 Of 1	[First] [Previou	s] [Next] [Las

Note:

Application resubmission is required for Primary IR but not for Secondary IR.

For Secondary IR, please response with your comments accordingly or else it will not be considered as submitted.

(3) Fill in any response in the text box for response to Secondary Input Request and click the 'Submit' button.



🥖 Input Reque	est List - Internet Explorer		A C grown		3
Attps://ww	w-uat. hsa.gov.sg /prism/common/I	nputReqActList/	list.do?action=list&irType=S&app_no=	1600771U&eService=130&NOTI	
INPUT REQ	UEST LIST (SECONDARY)				\sim
Application No	: 1600771U				
	with comments for each item in t nat resubmission of the applicati		nd submit this secondary input requ red.	uest.	
1 Records Action List					
SN	Action	Due Date	Applicant's Response (if any)		
1.	For Secondary Screenshot	15/07/2016		^	
				~	
				Submit Cancel	
					\checkmark

Other Useful Information

- 1. You may check on the status of your application upon submission at <u>track@prism</u>.
- 2. Kindly contact the HSA Helpdesk if you encounter any technical issues (IT problems) during the application submission.

HSA HelpDesk Tel : 6776 0168 (from 7:00 am to midnight daily) Email : <u>helpdesk@hsahelp.gov.sg</u>

3. For general enquiries or questions related to licences and certificates of manufacturers, importers and wholesalers, please contact the Audit and Licensing Division at Tel: 6866 1111 or write to https://crm.hsa.gov.sg/event/feedback.aspx